REMARKS

Prior to examination, the application has been reviewed to advance prosecution to an early allowance. The present amendment corrects an obvious typographical error in the Abstract of the Disclosure and reverses the subject matter of Claims 1 and 2 for the better readability thereof. No new matter is introduced into the application.

Responsive to the Notice To File Missing Parts of Nonprovisional Application mailed February 1, 2002, the formalities regarding the missing declaration and Sequence Listing are being addressed herein. A copy of the Notice is returned with this reply.

Firstly, two Combined Declarations and Powers of Attorney properly signed by all joint inventors in compliance with 37 C.F.R. § 1.63, identifying the application by the Application Number and Filing Date, are enclosed. It is noted that the separate declarations were needed as a consequence of the move of the co-inventor, Dr. Haqshenas, to Iran.

Secondly, to meet the requirements of 37 C.F.R. § 1.821-1.825, an initial paper copy of the Sequence Listing and a computer readable form (CRF) copy on computer disc are enclosed. As mandated, the present amendment directs the entry of the Sequence Listing into the application.

Pursuant to 37 C.F.R. § 1.821(f), it is hereby stated that the Sequence Listing information recorded in computer readable form is identical to the content of the written paper copy of the Sequence Listing. It is further stated in accordance with 37 C.F.R. § 1.821(g) that this submission does not include new matter.

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Accordingly, the record with respect to the formalities is now complete and the application is ready for examination. Favorable treatment is urged.

Respectfully submitted,
FORT DODGE ANIMAL HEALTH, INC.

Date: April 1, 2002 By: Anne M Rosenblum
Anne M. Rosenblum
Attorney for Applicants
Registration No. 30,419

FILING BY EXPRESS MAIL UNDER 37 C.F.R. § 1.10

This correspondence is being deposited with the U.S. Postal Service on April 1, 2002 to be delivered by the "Express Mail Post Office to Addressee" service under Mailing Label Number EK461082993US addressed to: Commissioner for Patents, Washington, D.C. 20231.

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APPENDIX

MARKED UP VERSION OF REWRITTEN CLAIM(S) AND ABSTRACT OF THE DISCLOSURE

1 (Amended). An isolated avian hepatitis E virus having no more than about 80% nucleotide sequence identity to an Australian big liver and spleen disease virus [a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand].

2 (Amended). The avian hepatitis E virus according to Claim 1, wherein said virus has a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand [no more than about 80% nucleotide sequence identity to an Australian big liver and spleen disease virus].

ABSTRACT OF THE DISCLOSURE

The present invention relates to a novel isolated avian hepatitis E virus having a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand. The invention further concerns immunogenic compositions comprising this new virus or [a] recombinant products such as the nucleic acid and vaccines that protect an avian or mammalian species from viral infection or hepatitis-splenomegaly syndrome caused by the hepatitis E virus. Also included in the scope of the invention is a method for propagating, inactivating or attenuating a hepatitis E virus comprising inoculating an embryonated chicken egg with a live, pathogenic hepatitis E virus and recovering the virus or serially passing the pathogenic virus through additional embryonated chicken eggs until the virus is rendered inactivated or attenuated. Further, this invention concerns diagnostic reagents for detecting an avian hepatitis E viral infection or diagnosing hepatitis-splenomegaly syndrome in an avian or mammalian species comprising an antibody raised or produced against the immunogenic compositions and antigens such as ORF2 proteins expressed in a baculovirus vector, *E. coli, etc.* The invention additionally encompasses methods for detecting avian HEV nucleic acid sequences using nucleic acid hybridization probes or oligonucleotide primers for polymerase chain reaction (PCR).

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Avian Hepatitis E Virus, Vaccines and Methods of Protecting Against Avian Hepatitis-Splenomegaly Syndrome and Mammalian Hepatitis E

ABSTRACT OF THE DISCLOSURE

The present invention relates to a novel isolated avian hepatitis E virus having a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand. The invention further concerns immunogenic compositions comprising this new virus or recombinant products such as the nucleic acid and vaccines that protect an avian or mammalian species from viral infection or hepatitis-splenomegaly syndrome caused by the hepatitis E virus. Also included in the scope of the invention is a method for propagating, inactivating or attenuating a hepatitis E virus comprising inoculating an embryonated chicken egg with a live, pathogenic hepatitis E virus and recovering the virus or serially passing the pathogenic virus through additional embryonated chicken eggs until the virus is rendered inactivated or attenuated. Further, this invention concerns diagnostic reagents for detecting an avian hepatitis E viral infection or diagnosing hepatitis-splenomegaly syndrome in an avian or mammalian species comprising an antibody raised or produced against the immunogenic compositions and antigens such as ORF2 proteins expressed in a baculovirus vector, *E. coli, etc.* The invention additionally encompasses methods for detecting avian HEV nucleic acid sequences using nucleic acid hybridization probes or oligonucleotide primers for polymerase chain reaction (PCR).